(c) Transportation activities which are regulated by the Department of Transportation;

(d) Activities conducted under the Nuclear Waste Policy Act of 1982, as amended, and any facility identified under section 202(5) of the Energy Reorganization Act of 1974, as amended; and

(e) Activities related to the launch approval and actual launch of nuclear energy systems into space.

§ 830.3 Definitions.

(a) The following definitions apply to this part:

Administrative controls means the provisions relating to organization and management, procedures, record-keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Bases appendix means an appendix that describes the basis of the limits and other requirements in technical safety requirements.

Critical assembly means special nuclear devices designed and used to sustain nuclear reactions, which may be subject to frequent core and lattice configuration change and which frequently may be used as mockups of reactor configurations.

Criticality means the condition in which a nuclear fission chain reaction becomes self-sustaining.

Design features means the design features of a nuclear facility specified in the technical safety requirements that, if altered or modified, would have a significant effect on safe operation.

Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results.

Documented safety analysis means a documented analysis of the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.

Environmental restoration activities means the process(es) by which contaminated sites and facilities are identified and characterized and by which contamination is contained, treated, or removed and disposed.

Existing DOE nuclear facility means a DOE nuclear facility in operation before April 9, 2001.

Fissionable materials means a nuclide capable of sustaining a neutron-induced chain reaction (*e.g.*, uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with:

(1) The relative importance to safety, safeguards, and security;

(2) The magnitude of any hazard involved;

(3) The life cycle stage of a facility;

(4) The programmatic mission of a facility;

(5) The particular characteristics of a facility;

(6) The relative importance of radiological and nonradiological hazards; and

(7) Any other relevant factor.

Hazard means a source of danger (*i.e.*, material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

Hazard controls means measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including

(1) Physical, design, structural, and engineering features;

(2) Safety structures, systems, and components;

(3) Safety management programs;

(4) Technical safety requirements; and

(5) Other controls necessary to provide adequate protection from hazards.

Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, or support systems.

Limiting conditions for operation means the limits that represent the

lowest functional capability or performance level of safety structures, systems, and components required for safe operations.

Limiting control settings means the settings on safety systems that control process variables to prevent exceeding a safety limit.

Low-level residual fixed radioactivity means the remaining radioactivity following reasonable efforts to remove radioactive systems, components, and stored materials. The remaining radioactivity is composed of surface contamination that is fixed following chemical cleaning or some similar process; a component of surface contamination that can be picked up by smears; or activated materials within structures. The radioactivity can be characterized as low-level if the smearable radioactivity is less than the values defined for removable contamination by 10 CFR Part 835, Appendix D, Surface Contamination Values, and the hazard analysis results show that no credible accident scenario or work practices would release the remaining fixed radioactivity or activation components at levels that would prudently require the use of active safety systems, structures, or components to prevent or mitigate a release of radioactive materials.

Major modification means a modification to a DOE nuclear facility that is completed on or after April 9, 2001 that substantially changes the existing safety basis for the facility.

New DOE nuclear facility means a DOE nuclear facility that begins operation on or after April 9, 2001.

Nonreactor nuclear facility means those facilities, activities or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.

Nuclear facility means a reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by this Part.

Operating limits means those limits required to ensure the safe operation of a nuclear facility, including limiting control settings and limiting conditions for operation.

Preliminary documented safety analysis means documentation prepared in connection with the design and construction of a new DOE nuclear facility or a major modification to a DOE nuclear facility that provides a reasonable basis for the preliminary conclusion that the nuclear facility can be operated safely through the consideration of factors such as

(1) The nuclear safety design criteria to be satisfied;

(2) A safety analysis that derives aspects of design that are necessary to satisfy the nuclear safety design criteria; and

(3) An initial listing of the safety management programs that must be developed to address operational safety considerations.

Process means a series of actions that achieves an end or result.

Quality means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality assurance means all those actions that provide confidence that quality is achieved.

Quality Assurance Program (QAP) means the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Reactor means any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner such as research, test, and power reactors, and critical and pulsed assemblies and any assembly that is designed to perform subcritical experiments that could potentially reach criticality; and, unless modified by words such as containment, vessel, or core, refers to

the entire facility, including the housing, equipment and associated areas devoted to the operation and maintenance of one or more reactor cores.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Safety basis means the documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment.

Safety class structures, systems, and components means the structures, systems, or components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses.

Safety evaluation report means the report prepared by DOE to document

(1) The sufficiency of the documented safety analysis for a hazard category 1, 2, or 3 DOE nuclear facility;

(2) The extent to which a contractor has satisfied the requirements of Subpart B of this part; and

(3) The basis for approval by DOE of the safety basis for the facility, including any conditions for approval.

Safety limits means the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials.

Safety management program means a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.

Safety management system means an integrated safety management system established consistent with 48 CFR 970.5223–1.

Safety significant structures, systems, and components means the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.

Safety structures, systems, and components means both safety class structures, systems, and components and safety significant structures, systems, and components.

Service means the performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, waste management, laboratory sample analyses, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Surveillance requirements means requirements relating to test, calibration, or inspection to ensure that the necessary operability and quality of safety structures, systems, and components and their support systems required for safe operations are maintained, that facility operation is within safety limits, and that limiting control settings and limiting conditions for operation are met.

Technical safety requirements (TSRs) means the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: Safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Unreviewed Safety Question (USQ) means a situation where

(1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased;

(2) The possibility of an accident or malfunction of a different type than

any evaluated previously in the documented safety analysis could be created;

(3) A margin of safety could be reduced; or

(4) The documented safety analysis may not be bounding or may be otherwise inadequate.

Unreviewed Safety Question process means the mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question.

Use and application provisions means the basic instructions for applying technical safety requirements.

(b) Terms defined in the Act or in 10 CFR part 820 and not defined in this section of the rule are to be used consistent with the meanings given in the Act or in 10 CFR part 820.

§ 830.4 General requirements.

(a) No person may take or cause to be taken any action inconsistent with the requirements of this part.

(b) A contractor responsible for a nuclear facility must ensure implementation of, and compliance with, the requirements of this part.

(c) The requirements of this part must be implemented in a manner that provides reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards.

(d) If there is no contractor for a DOE nuclear facility, DOE must ensure implementation of, and compliance with, the requirements of this part.

§ 830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of 10 CFR part 820.

§ 830.6 Recordkeeping.

A contractor must maintain complete and accurate records as necessary to substantiate compliance with the requirements of this part.

§ 830.7 Graded approach.

Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

Subpart A—Quality Assurance Requirements

§ 830.120 Scope.

This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services, that affect, or may affect, nuclear safety of DOE nuclear facilities.

§ 830.121 Quality Assurance Program (QAP).

(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in § 830.122.

(b) The contractor responsible for a DOE nuclear facility must:

(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.

(2) Modify the QAP as directed by DOE.

(3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.

(4) Conduct work in accordance with the QAP.

(c) The QAP must:

(1) Describe how the quality assurance criteria of § 830.122 are satisfied.

(2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.